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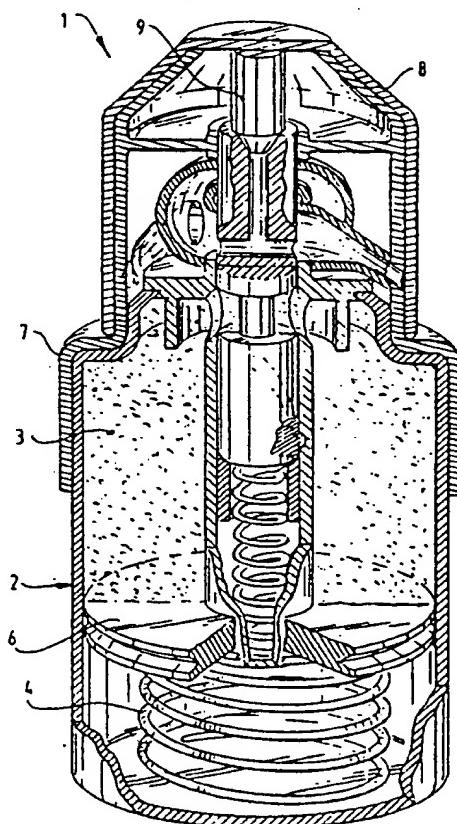
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(72) Inventors; and (75) Inventors/Applicants (for US only) : ZANEN, Pieter [NL/NL]; Sikkelderveld 27, NL-3993 RH Houten (NL). PLOMP, Adrianus [NL/NL]; Hulstweg 70, NL-1871 TJ Schoorl (NL). BOON, Gerhardus, Anthonus [NL/NL]; Haremakers 52, NL-1531 LC Wormer (NL). VAN SWIETEN, Roy [NL/NL]; Kerkstraat 18, NL-5253 AP Nieuwkuyk (NL).		(88) Date of publication of the international search report: 14 May 1992 (14.05.92)

(54) Title: INHALER DEVICES PROVIDED WITH A RESERVOIR FOR SEVERAL DOSES OF MEDIUM FOR INHALING, TRANSPORTING DEVICE, WHIRL CHAMBER

(57) Abstract

The present invention provides an inhaler device (1) for inhaling an aerosol in a desired dosage, comprising a housing (2) in which is received a reservoir (3) of powder or liquid, an inhaling piece (7) placed on the housing and means for transporting the powder or liquid from the reservoir to the inhaling piece in a dosage required for the aerosol. The transporting mechanism can be a spring loaded plunger (11) with a toroidal space along its walls, that is filled by the medication when the plunger is pushed down, and that brings the medication into a whirl mixing chamber (16, 55), when it is pushed upwards by the spring. In another embodiment the transport mechanism can be a worm (56), hand rotated, in order to transport medication from the reservoir into the whirl mixing chamber (16, 55). The whirl mixing chamber (55), activated by the patient's inhaling, has two feed channels (62-63), one to transport the medication into the chamber, the other to cross the first one at right angles to disrupt the flow and enhance medication mixing.



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INHALER DEVICES PROVIDED WITH A RESERVOIR FOR SEVERAL DOSES OF MEDIUM FOR INHALING, TRANSPORTING DEVICE, WHIRL CHAMBER

The present invention relates to inhaler devices, in particular inhaler devices with which several doses can be administered. With such inhaler devices an aerosol is administered as medicine to the lungs, particularly the 5 alveolar zone, by inhalation through nose or mouth.

Existing systems typically provide a single dose of an aerosol, whereafter a capsule is thrown away, which is harmful to the environment. Inhaler devices, for instance for CNSLD patients, wherein at each inhalation a capsule is 10 placed therein, are frequently used in practice.

Inhaler devices for several doses are still only commercially available on a limited scale. There are problems with these known inhaler devices in respect of their manageability and size, the required suction force on 15 a mouth or nose piece and/or the accuracy of dosing.

Known inhaler devices for several doses are awkward to use and/or consist of a relatively large number of components, whereby manufacture becomes time-consuming and expensive. Such an inhaler device is known from EP-A-211595.

20 A first aspect of the present invention provides an inhaler device for inhaling an aerosol in a desired dosage, comprising a housing in which is received a reservoir of powder or liquid, an inhaling piece placed on the housing and means for transporting the powder or liquid from the 25 reservoir to the inhaling piece in a dosage required for the aerosol.

A second aspect of the present invention has for its object to obviate one or more of the above stated problems and provides a device for inhaling an aerosol, comprising:

30 - a reservoir for storing a supply of medium for inhaling;

- an inhaling piece for sucking air along a dose of medium for inhaling; and

- transporting means for transporting a dose of medium for inhaling out of the reservoir, wherein a whirl chamber is incorporated in the inhaling piece for taking up the medium into the indrawn air with only a small suction force.

The present invention provides an inhaler device that can be used in different positions. The operation of the inhaling piece, the transporting means and/or the whirl chamber are not adversely affected by the position of the 10 inhaler device relative to the direction of the force of gravity.

The whirling and high speed of the air are advantageous in obtaining particles for inhaling of a sufficiently small diameter (for instance smaller than 7, 5 or 1 μm). The 15 medium in the reservoir usually also comprises carrier material to cause the medium to flow easily, particularly from the reservoir to the whirl chamber where the particles for inhaling are then separated from the carrier particles (of usually greater diameter) by the shear forces generated by 20 the air. Also in the case the medium for inhaling does not comprise any carrier material, shear forces have to be applied thereto, since such inhaling medium is composed of complexes of relatively large diameter, for instance greater than 7 μm . For inhalation into the alveolar zone the 25 particle diameter also has to be reduced. With both types of medium there normally remains a non-inhalable fraction of for example 20% by vol.

Transporting of the medium for inhaling preferably takes place by means of a screw or worm since, as has been 30 found in tests, an accurate dose of medium can be transported herewith.

Further preferred embodiments relate to the desired whirling of the air and the compactness of the inhaler device; such embodiments are specified in claims 10-15.

35 In preference the inhaler device comprises two or more mutually interchangeable reservoirs with different medium. A patient then only needs to carry one inhaler device on his/ her person, even when (s)he has to inhale

different types of medium. Such reservoirs can be provided in simple manner with a bayonet fitting for coupling to the remaining part of the inhaler device according to the present invention.

- 5 Inhaler devices provided with a mixing chamber, wherein at each inhalation a capsule with a dose of medium is introduced, in addition to a reservoir for several doses of medium for inhaling are widely available, for instance for CNSLD patients. The medium for inhaling typically
10 comprises a powder which during inhalation must be present in the air in a particular diameter of for instance less than 10 μm , or less than 7, 5 or 1 μm . To improve the transporting properties of the powder, carrier material can be incorporated therein with a particle diameter greater
15 than the above mentioned diameter. Also when no carrier material is included in the powder, complexes of particles occur easily in the aerosol which have a diameter greater than above stated. Particles with a greater diameter than the above stated are undesirable in the aerosol as they
20 cannot exert any medicinal effect but can still result in irritations of the bronchial tubes, oral cavity and/or pharynx.

A third aspect of the present invention provides an inhaler device for inhaling an aerosol, comprising:

- 25 - a suction piece for sucking in the aerosol;
 - a mixing chamber for mixing sucked in air and medium for taking up air; and
 - separating means for separating that fraction of the aerosol whereof the particles have a diameter greater
30 than a predetermined value.

It will be apparent that the present invention is not limited to the case wherein the medium is in powder form. Use of the device according to the present invention is equally conceivable for vaporized (liquid) medium.

- 35 Further advantages, features and details of the present invention will be elucidated in the light of a description of preferred embodiments thereof with reference to the annexed drawing, in which:

Fig. 1 shows a view, partly in section and partly in perspective, of a preferred embodiment according to the present invention in closed situation;

Fig. 2 is the view of fig. 1 in the ready-for-use situation;

Fig. 3 shows a view, partly in section and partly in perspective, of the embodiment of fig. 1 and 2 for elucidation of several details thereof;

Fig. 4 shows a view of an element to be included in 10 the embodiment of fig. 1-3;

Fig. 5 shows a partly broken away view in perspective of a second preferred embodiment of the inhaler device according to the present invention;

Fig. 6 is a view, partly in perspective and partly in 15 section, of detail II of fig. 5; and

Fig. 7A and 7B respectively show elements which can be incorporated in the embodiment as shown in fig. 5 and 6; and

Fig. 8 shows a side view of a third embodiment, 20 partly in section, of the inhaler device according to the present invention.

An inhaler device 1 (fig. 1-3) according to the present invention comprises a housing 2 in which a reservoir 3 of inhalable material, which is medicinal in the 25 embodiment shown, is held in a compressed state. Placed on the housing 2 is an inhaling piece 7, for example joined thereto in a manner not shown with a snap-on connection, so that after the reservoir has been emptied the inhaling piece can be placed on a new reservoir. The inhaling piece 7 is 30 intended for placing on nose or mouth in order to be then sucked on. Placed over the inhaling piece 7 is a removable closing cap 8 provided with a protruding pin 9.

As will be apparent particularly from fig. 2, when the closing cap 8 is removed, a plunger 11 is moved upward 35 by means of the spring force of a second coil spring 12. The plunger 11 is provided with a recess between a top piece 13 and a bottom piece 14, wherewith a dose of powder can be transported in the desired dosage from the reservoir to a

mixing space 16. As is indicated with the arrows, when the opening 17 is sucked on, suction takes place through three channels, of which the channels 18 and 19 are visible in the figure, and via whirling of the air a good mixing of the 5 powder and the air is obtained in the desired manner.

In preference the pin portion 9 of the closing cap 8 is provided with a tapering portion which fits into the conical opening 17 so that when the closing cap 8 is arranged the up and downward movable plunger 11 provided 10 with a central channel 21 and the recess can be moved into the rest position shown in fig.1.

For guiding the powder to the recess in the plunger the housing 2 is preferably provided with an upper piece 22 provided with collar-like portion 23 which protrudes into 15 the powder reservoir.

So that the powder-form material is carried well by the plunger, the latter is provided with a protrusion guided in a groove 24 that is arranged in the cylinder-shaped guiding 25 for the plunger, wherein this groove 24 causes 20 the plunger to rotate slightly.

In a further embodiment of the present invention (not shown), a shaft 40 provided with wing-like elements 41 can be included at the centre line of the device shown in fig. 1-3. Preferably a rotating mechanism is provided such that 25 for every dose shaft 40 is rotated and powder is stirred by elements 41 whereby the flow of the powder is improved. The rotating mechanism can correspond to such mechanism as used in a ballpoint-pen for rotating the writing element thereof.

The present inhaler device is suitable for giving a 30 large number of doses and therefore for prolonged use. It can be manufactured from a comparatively small number of components, preferably of plastic.

A second embodiment an inhaler device 51 (fig.5) is provided with a part 52 (fig.5, fig.6) in which is received 35 a reservoir 53 for medium for inhaling in addition to a transporting mechanism 54 for transporting the medium out of the reservoir to a whirl chamber 55. The material for inhaling comprises carrier particles which are of minor

importance in the effect on the bronchial tubes of a patient. These carrier particles are necessary however in order to prevent the medium M for inhaling from coagulating and thereby becoming barely transportable.

5 For transporting the medium M in doses of precise size a screw or worm 56 is preferably used which can be operated using a rotating knob 57. It has been found in tests that such a transporting mechanism is capable of transporting a medium M with an accuracy of less than 5% out
10 of the reservoir 53 into the whirl chamber 55 at each revolution of the opening 58 away from and up to a closing member 59 for this opening.

The inhaler device is provided with an inhaling piece 11 for sucking in air via the nose or mouth of a patient
15 along two feed channels 62 and 63 which are arranged in a peripheral wall 64 of the inhaler device. A flow of air, as designated with arrows F_1 , carries the medium brought into the whirl chamber 55 under cover plate 65 along a guide means 66 and then collides with the air flow designated with
20 arrow F_2 which is drawn in along feed channel 63. With a comparatively small suction force great air speeds occur here, in addition to whirls when these air flows F_1 and F_2 collide with one another. Shear forces hereby occur which separate the particles with medicinal effect from the
25 carrier particles which usually have a greater diameter than that of the medicinal particles.

The member 16 for guiding the air (fig.7A) is provided on the side facing the feed channel 62 with a rounded form, while the side facing the feed channel 63 is sharp-edged and the angle is formed by flat wall portions 67 and 68 so that the air flow F_2 collides with the air flow F_1 transversely.

In a further embodiment (not shown), the inhaler device according to the present invention is provided with a
35 guide means 71 for guiding the air (fig.7B) partially similar to the guide means 66, but which is additionally provided with an air guide portion 72 rising in the direction of the inhaling piece 11 and preventing unwanted

air, as indicated with arrow F_3 in fig. 1, on the side of the guide means 71 remote from the doses of medium for inhaling from passing into the inhaling piece 11. An inhaler device provided with such a guide means 71 therefore 5 requires an even smaller suction force, which is particularly important in the case of children and older patients with lung disorders.

The inhaler device according to the shown and described embodiment has, among others, the following advantages:

- 10 - the inhaler device is compact of structure and has a size such that it can easily be held in the hand;
- the inhaler device can be used in any desired position, with the inhaling piece horizontal or oriented upward or downward;
- 15 - the inhaler device requires little suction force, while great shear forces are applied to the medium or powder so that the medicinal particles are released from the carrier particles.

A third embodiment of an inhaler device 81 (fig. 8) 20 according to the present invention comprises a schematically designated mixing chamber 82 in which a dosage for inhaling is mixed with air drawn into the mixing chamber 82 in a manner not shown. The inhaler device 81 can further be provided with a reservoir in which is received a supply of 25 medium for inhaling, in addition to transporting means, likewise not shown, for transporting one dose of medium at a time out of this reservoir into the mixing chamber.

Coupled to the mixing chamber 82 is a suction piece 83 comprising an inlet channel 84, an outlet channel 85 and 30 a collecting chamber 86. The suction piece 87 is sucked on by the patient via nose or mouth. A fraction of the aerosol, designated with arrow B_2 whereof the particles have a comparatively large diameter, for example greater than 10, 7, 5 or 1 μm , does not however reach the outlet channel 85 35 of the mass of the particles. These particles from the fraction B_2 are collected at the bottom of the collecting chamber 86 which must be emptied from time to time by releasing the cover 88.

With the inhaler device (third embodiment) according to the present invention now proposed and still to be realized in practice, the angle enclosed by the centre lines of the outlet channel 85 and the inlet channel 84 has a 5 value of approximately 60° , that is, the change of direction amounts to roughly 120° . The inlet channel is initially envisaged as having a diameter of approximately 1 cm, the outlet channel as having a diameter of 0.8 cm and the inlet channel as having a length of about 5 cm. The preferred 10 embodiment shown is preferably realized in plastic. The figure is drawn to scale so that other proposed dimensions can be derived therefrom.

The present invention is not limited to the preferred embodiment shown and described. The rights are determined by 15 the claims following hereinafter.

CLAIMS

1. Device for inhaling an aerosol, comprising:
 - a housing in which is receive a reservoir of powder or liquid,
 - an inhaling piece placed on the housing; and
 - means for transporting the powder or liquid from the reservoir to the inhaling piece in a dose required for the aerosol.
- 5 2. Inhaler device as claimed in claim 1, wherein the transporting means comprise a plunger which is provided with a recess and which is movable reciprocally counter to the pressure of a spring.
- 10 3. Inhaler device as claimed in claim 1 or 2, wherein the reservoir is provided with powder.
- 15 4. Inhaler device as claimed in claim 1,2 or 3, wherein a piston and spring are incorporated in the housing for holding the content of the reservoir in compressed state.
- 20 5. Inhaler device as claimed in any of claims 1-4, wherein the transporting means are reciprocally movable by means of a closing cap for placing on the inhaling piece, wherein when this closing cap is removed, a dose is transported to the inhaling piece.
- 25 6. Inhaler device as claimed in any of claims 2-5, wherein the plunger is provided with protrusion for causing the plunger to rotate relative to the housing.
7. Inhaler device as claimed in any one of claims 2-6, in which rotatable stirring elements or wing-like elements extend in the recess.
- 30 8. Device for inhaling an aerosol, comprising:
 - a reservoir for storing a supply of medium for inhaling;
 - an inhaling piece for sucking air along a dose of medium for inhaling; and
 - transporting means for transporting a dose of medium for inhaling out of the reservoir, wherein a whirl
- 35

chamber is incorporated in the inhaling piece for taking up the medium into the indrawn air with only a small suction force.

9. Inhaler device as claimed in claim 8, wherein the
5 transporting means comprise a screw or worm.

10. Inhaler device as claimed in claim 8 or 9 provided with a piston which is under spring pressure and in turn holds the medium for inhaling under a certain pressure.

11. Inhaler device as claimed in claim 8, 9 or 10,
10 wherein the whirl chamber is embodied such that air drawn in through a first opening moves along the dose of medium for inhaling and subsequently collides with an air flow drawn in along a second opening, wherein a whirling is excited such that the active constituents of the medium are released to a
15 sufficient extent with sufficiently small diameter.

12. Inhaler device as claimed in any of the claims 8-
11, wherein a mouth or nose piece of the inhaling piece is disposed eccentrically of the centre line of the inhaler device.

20 13. Inhaler device as claimed in any of the claims 8-
12, wherein a guide means for guiding the air flow is arranged in the vicinity of the centre of the inhaling piece.

25 14. Inhaler device as claimed in claim 13, wherein the guide means is provided with a rounded portion and with a sharp-edged portion.

15. Inhaler device as claimed in claim 13 or 14, wherein the guide means is provided with a guide portion for guiding the air flow upward to the mouth or nose piece.

30 16. Inhaler device as claimed in any of the claims 8-
15 provided with two or more mutually interchangeable reservoirs with different medium.

35 17. Transporting device for transporting powder for pharmaceutical or cosmetic purposes, provided with a screw or worm.

18. Transporting device as claimed in claim 17, wherein the screw or worm protrudes through a reservoir for

the powder, wherein the powder in the reservoir is pressed by a piston standing under spring tension.

19. Whirl chamber for an inhaler device provided with air channels such that a first air flow is guided along 5 medium or powder and a second air flow collides with the first air flow in substantially transverse direction.

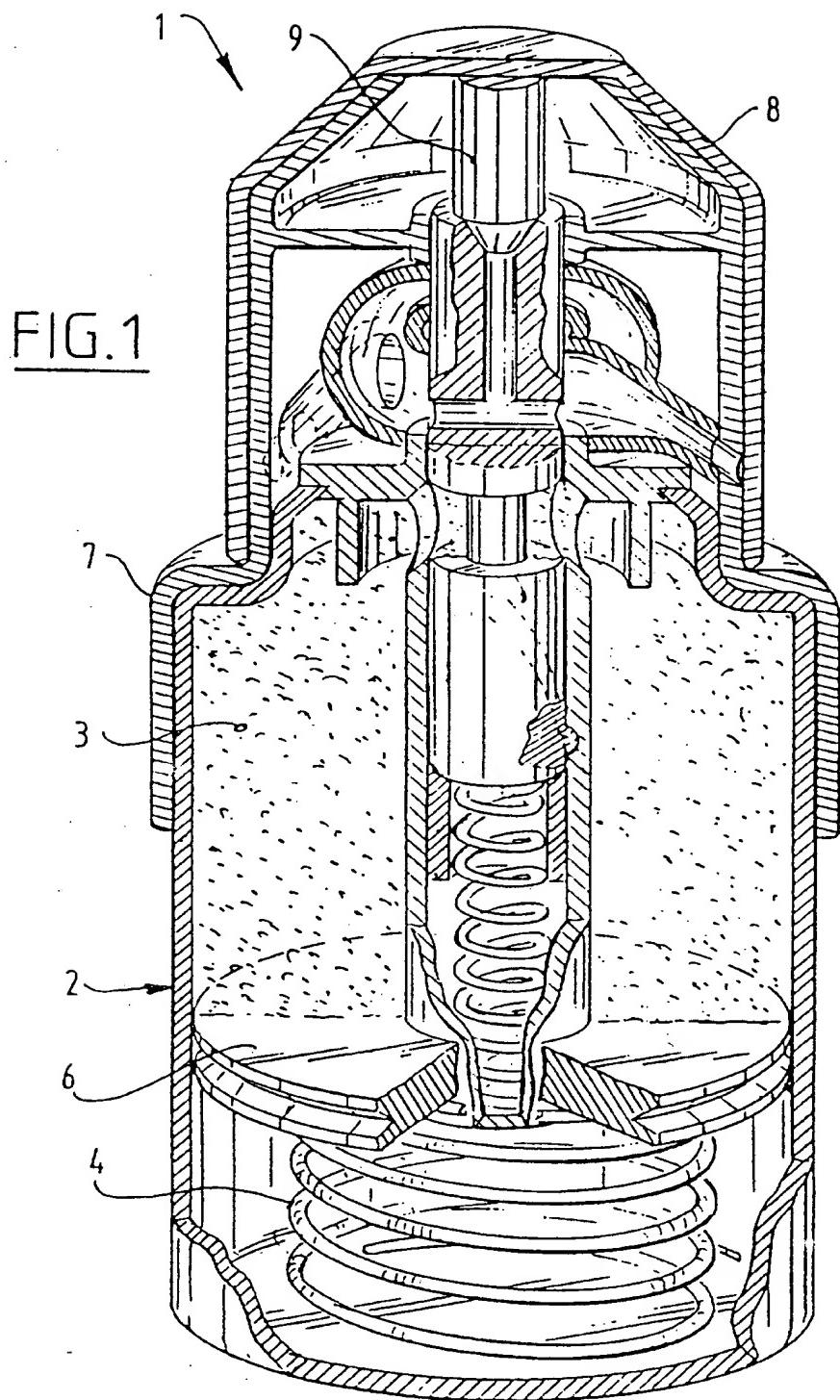
20. Inhaler device for inhaling aerosol, comprising:
- a suction piece for sucking in an aerosol;
- a mixing chamber for mixing sucked in air and
10 medium for taking up in the air; and
- separating means for separating that fraction of the aerosol whereof the particles have a diameter greater than a predetermined value.

21. Inhaler device as claimed in claim 20, wherein 15 the separating means comprise an inlet channel and an outlet channel, wherein the centre lines of inlet and outlet channels enclose an acute angle.)

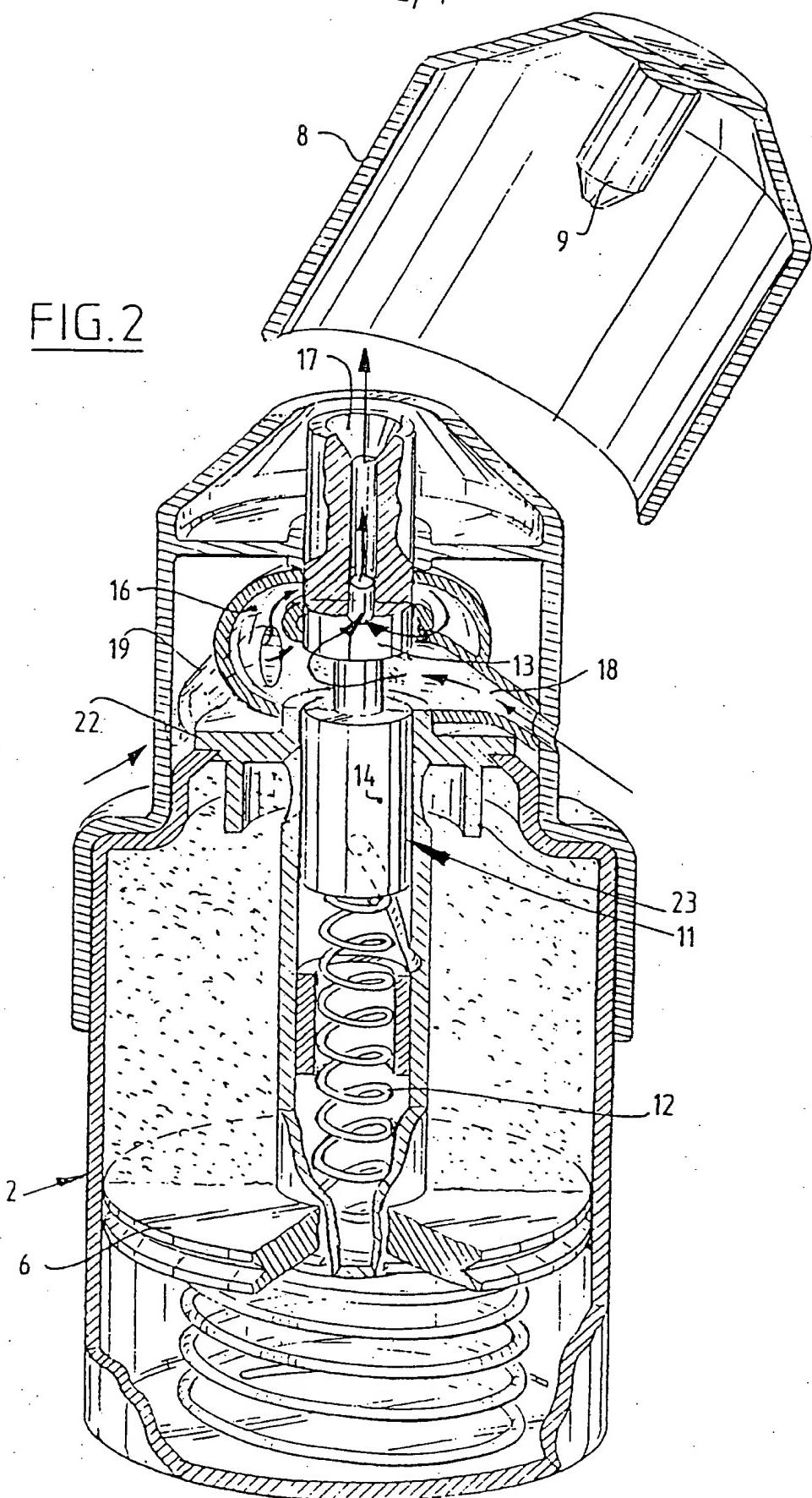
22. Inhaler device as claimed in claim 20 or 21, provided with a collecting reservoir for collecting the 20 fraction with a relatively large particle diameter.

23. Inhaler device as claimed in claim 22, wherein the reservoir is provided with a releasable cover.

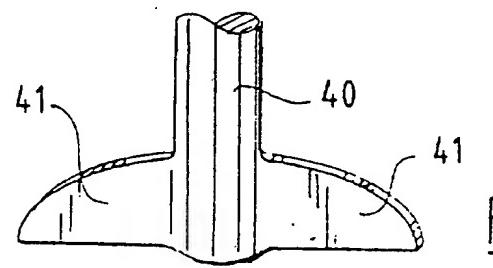
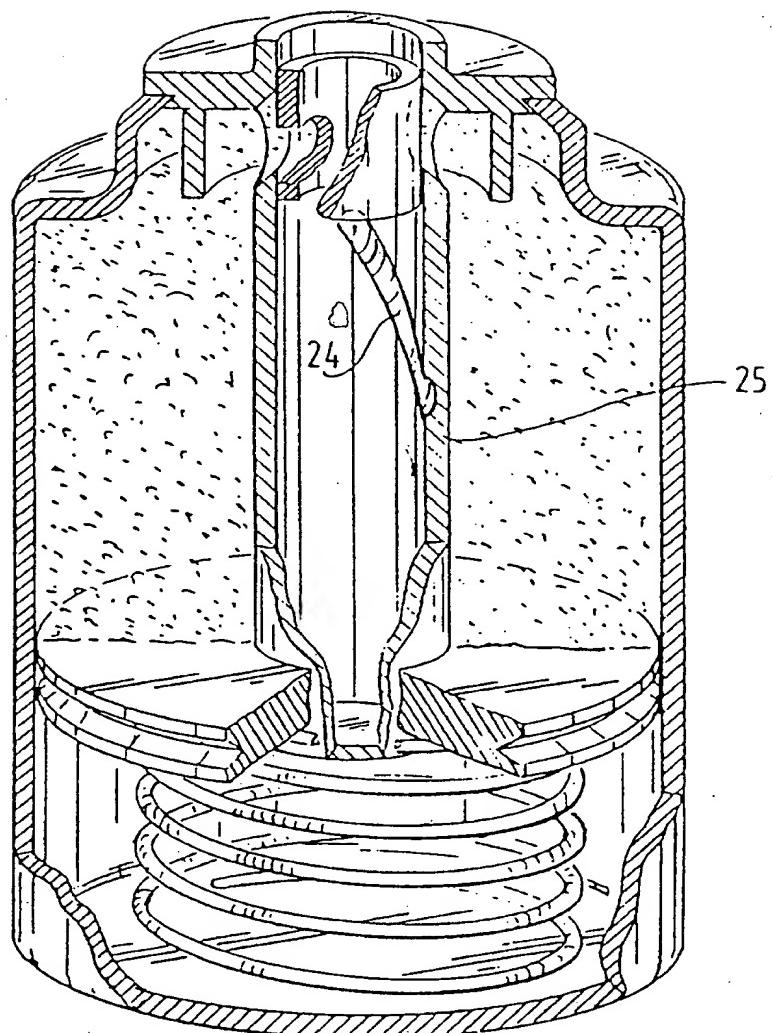
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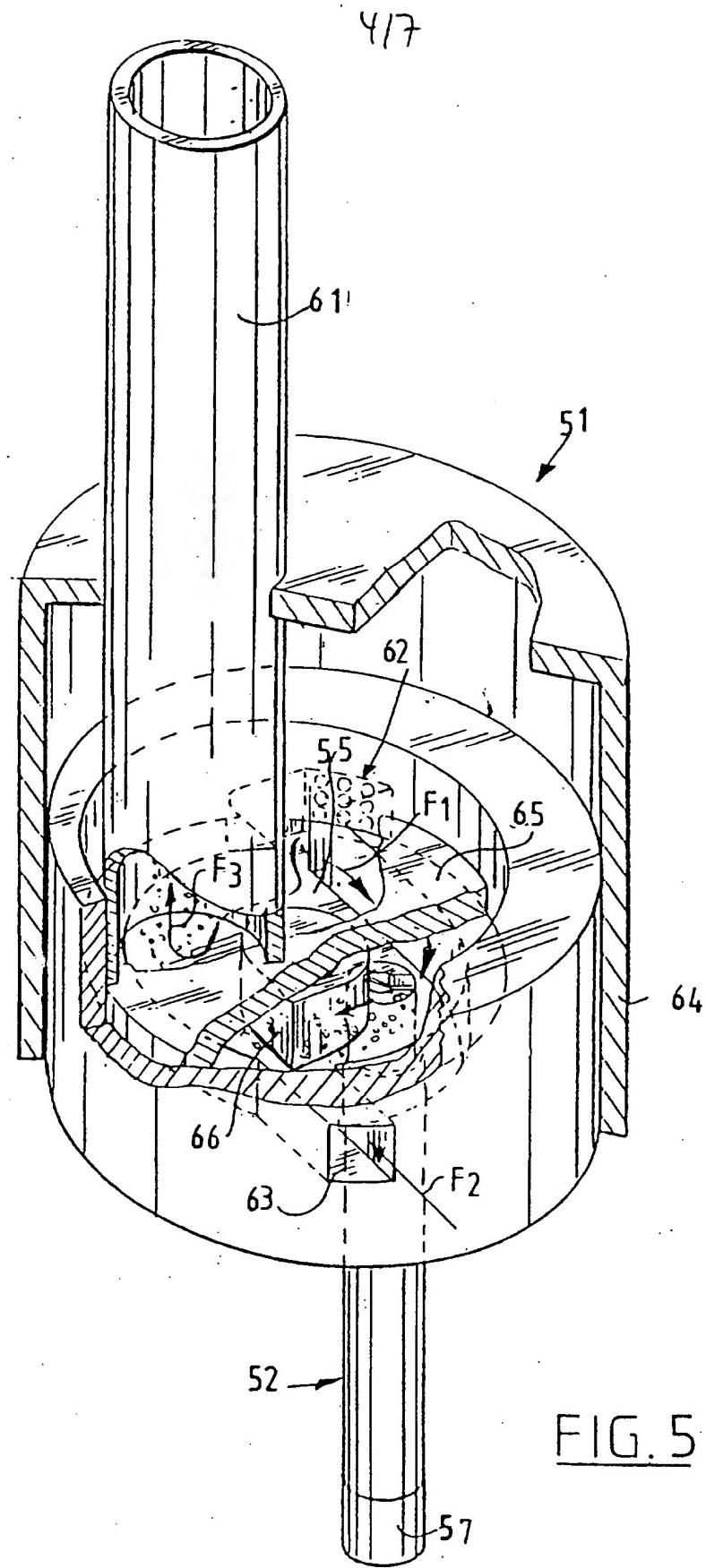


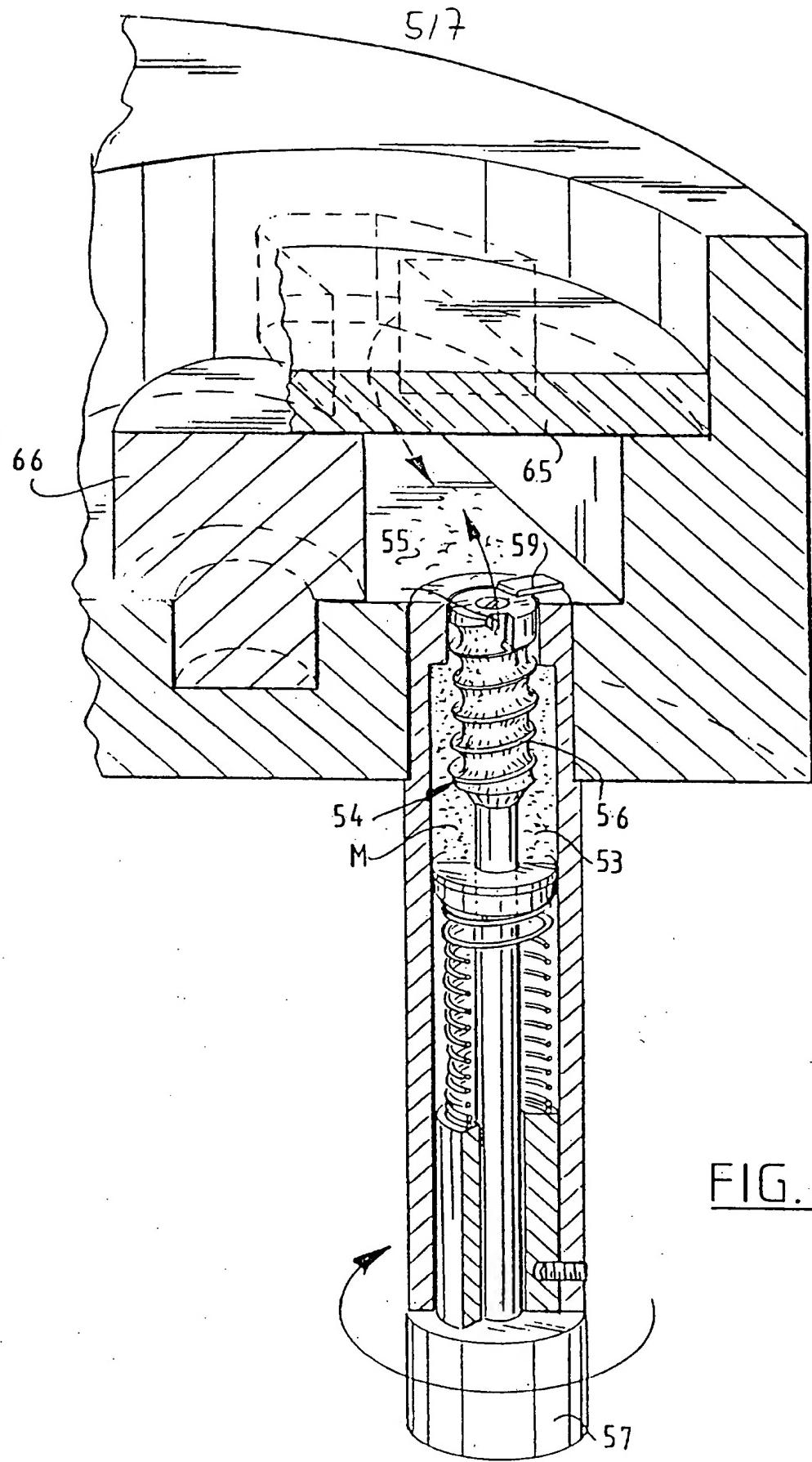
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FIG.3FIG.4





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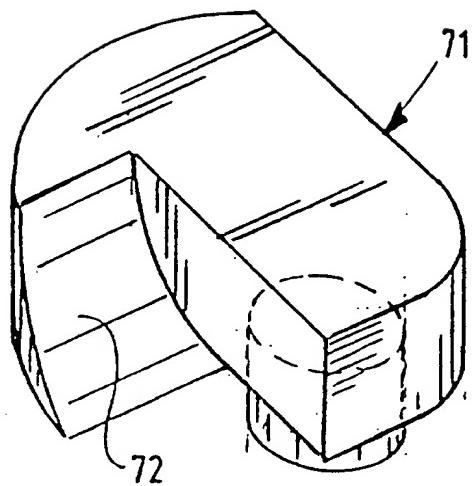


FIG. 7B

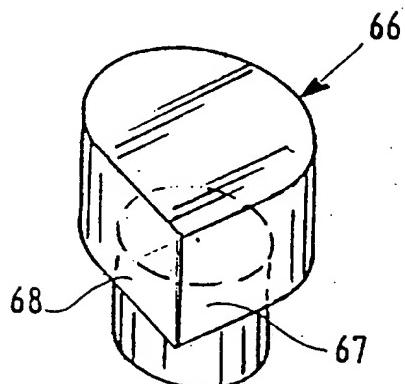


FIG. 7A

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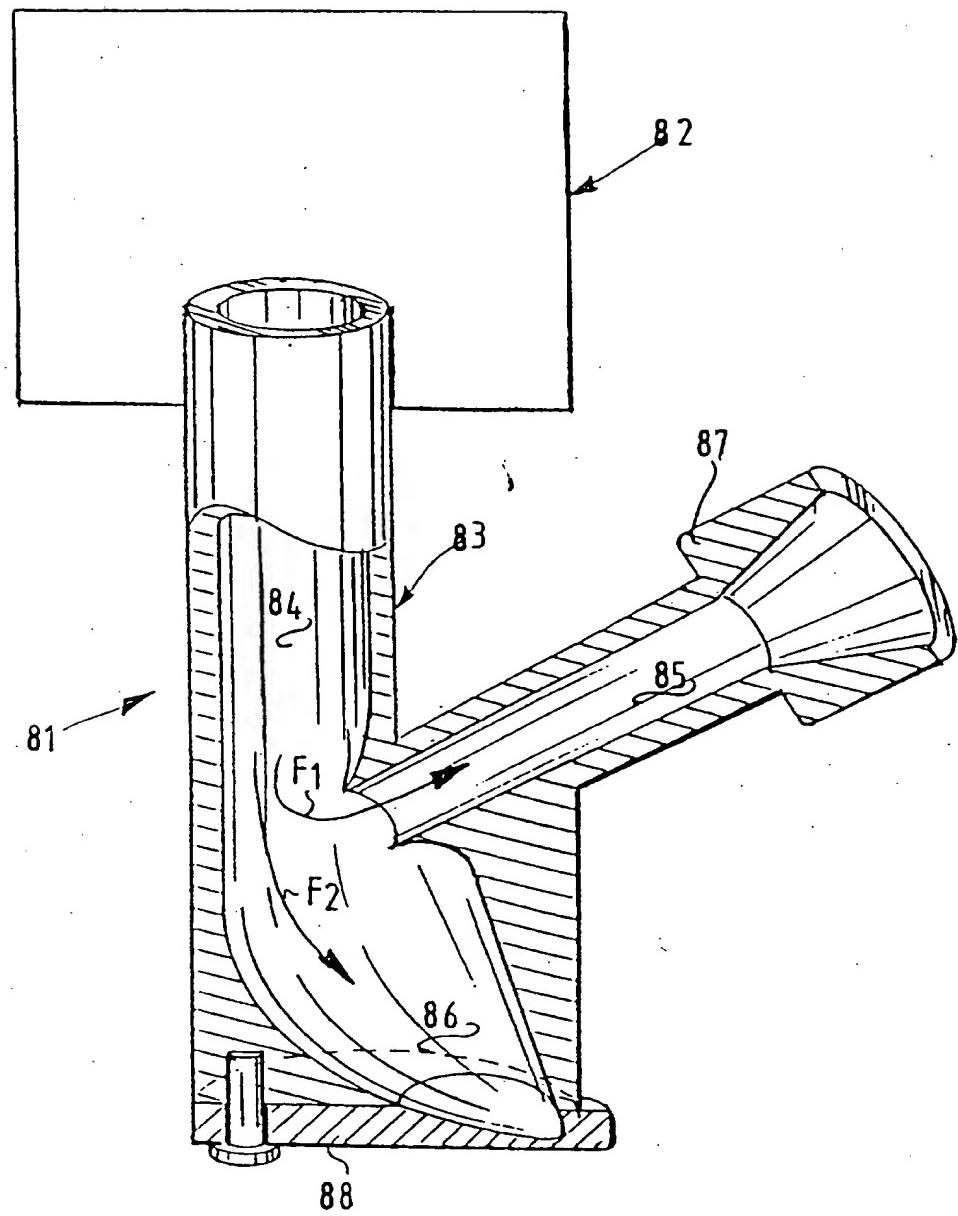


FIG. 8

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/EP 91/01884

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)⁶

According to International Patent Classification (IPC) or to both National Classification and IPC
Int.C1.5 A 61 M 15/00

II. FIELDS SEARCHED

Minimum Documentation Searched⁷

Classification System	Classification Symbols		
Int.C1.5	A 61 M	B 65 D	G 01 F

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched⁸

III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹

Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	US,A,4274403 (STRUVE) 23 June 1981, see abstract; page 2, column 5, lines 13-28; figures 2,3,6	1-3
Y	---	6
Y	FR,A,2489116 (L'OREAL) 5 March 1982, see claim 6; figure 4	6
X	DE,A,4004904 (BRENDEL) 13 September 1990, see the whole document	1,3,4, 20,21
A	---	10,22
Y	---	18

* Special categories of cited documents :¹⁰

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
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- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same parent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search

09-03-1992

Date of Mailing of the International Search Report

03.04.92

International Searching Authority

EUROPEAN PATENT OFFICE

Signature of Authorized Officer

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim
X	GB,A,2165159 (ORION YHTYMA OY) 9 April 1986, see page 2, lines 5-15; figure 2; abstract ---	1
A	GB,A,2165159 ---	2,5
Y	GB,A,1118341 (FISONS) 3 July 1968, see page 1, lines 36-50; page 1, line 81 - page 2, line 28; figures 1,2 ---	8,9,11
X	FR,A,2598918 (UNIVERSITE LILLE) 27 November 1987, see page 3, lines 9-14, 36-39; page 5, lines 22-28; page 6, lines 10-13; figures 2,1 ---	19
Y	FR,A,2598918 (UNIVERSITE LILLE) 27 November 1987, see page 3, lines 9-14, 36-39; page 5, lines 22-28; page 6, lines 10-13; figures 2,1 ---	8,9,11, 18
X	US,A,2581182 (FIELDS) 1 January 1952, see the whole document ---	17
A	US,A,1459478 (PAGE) 19 June 1923, see figures 3,4 ---	2
A	FR,A,2347939 (FABRE) 10 November 1977, see page 2, lines 22-30; figure 1 -----	8,9,17

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. OBSERVATION WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE¹

This International search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claim numbers
Authority, namely:

because they relate to subject matter not required to be searched by this
2. Claim numbers
Authority, namely:

because they relate to parts of the International application that do not comply with the prescribed requirements to such an extent that no meaningful International search can be carried out, specifically:
3. Claim numbers
Authority, namely:

the second and third sentences of PCT Rule 6.4(a).

because they are dependent claims and are not drafted in accordance with

VI. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING²

This International Searching Authority found multiple inventions in this International application as follows:

FOR FURTHER INFORMATION PLEASE SEE FORM PCT/ISA/206 SENT TO YOU 23-01-92.

1. As all required additional search fees were timely paid by the applicant, this International search report covers all searchable claims of the International application
2. As only some of the required additional search fees were timely paid by the applicant, this International search report covers only those claims of the International application for which fees were paid, specifically claims:
3. No required additional search fees were timely paid by the applicant. Consequently, this International search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:
4. As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- The additional search fees were accompanied by applicant's protest.
 No protest accompanied the payment of additional search fees.

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

EP 9101884

SA 51665

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 02/04/92. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A- 4274403	23-06-81	None		
FR-A- 2489116	05-03-82	None		
DE-A- 4004904	13-09-90	AU-A- 7236791 WO-A- 9112040	03-09-91 22-08-91	
GB-A- 2165159	09-04-86	CH-A- 666823 DE-A- 3535561 JP-A- 61090674 SE-A- 8504541	31-08-88 22-05-86 08-05-86 05-04-86	
GB-A- 1118341		None		
FR-A- 2598918	27-11-87	None		
US-A- 2581182		None		
US-A- 1459478		None		
FR-A- 2347939	10-11-77	CH-A- 609569 GB-A- 1515265	15-03-79 21-06-78	

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